REMARKS

Claims 21 to 40 are pending in this application. Claims 1 to 20 are cancelled. Claims 21 to 39 are currently amended. Claim 40 is new.

The Applicant gratefully acknowledges that the Examiner has indicated claims 27-29 and 32 recite allowable subject matter. The Applicant refers, in particular, to the Examiner's conclusion that "the prior art neither discloses nor fairly teaches the structural and/or temperature limitations set forth in [claims 27-29 and 32] in combination with the other recited limitations."

However, the Applicant respectfully disagrees with the Examiner regarding the rejection of claim 21-26, 30, 31, and 33-39. Therefore, reconsideration of this application is respectfully requested based on the foregoing amendments to the claims and the following remarks.

Claims 21-26, 30, 31, 33-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over French Patent No. 2,193,478 to Veillard in view of various U.S. Patents and Published Applications. The Examiner asserts that Veillard teaches a method of checking the leaktightness of a sealed container. U.S. Patent No. 4,803,868 to Vinton is cited for teaching the desirability of hermetically sealing pharmaceutical pill packs and in-process testing. U.S. Published Application No. 2001/0016059 to Krahn is cited for teaching "a polypropylene container having an aluminum foil cover." U.S. Patent No. 5,939,619 to Achter is cited for teaching "the application of appropriate pressure ranges when introducing a tracer gas into a sealed flexible package containing a metal foil." U.S. Patent No. 6,067,844 to

Westbrook is cited for teaching "the opening and removal of gas being carried out in a single step."

The primary reference cited against the present invention, *i.e.*, Veillard, teaches a process in which the piece to be inspected (*i.e.*, the container) is sealed by an impermeable plug and placed in a tank containing a given gas. The pressure in the tank is the same or greater than the pressure inside the container. To create the required pressure difference, a vacuum can be created inside the container before the container is sealed. After the "treatment time," the impermeable plug is opened and, if a vacuum has been created in the container, outside air penetrates the container. For the purpose of determining the presence or absence of the given gas in the container, a sample of the air in the container is withdrawn and injected into a gas detector. As acknowledged by the Examiner, Veillard does not teach sealed containers holding pharmaceutical substances and comprising foil-covered blister packs.

Vinton teaches a method of testing hermetically sealed packages, such as pharmaceutical pill packs of the type which have metal foil or metallic laminate in the material of the package. As stated in Vinton at column 1, lines 11-12, it is desirable for pharmaceutical pill packs to be hermetically sealed. The method of Vinton relies on the property of flexible sealed packages to expand when placed in a partial vacuum (col. 1, lines 26-28). Accordingly, Vinton provides a method of testing flexible sealed packages of the type wherein the packing is at least partially made of an electrically conductive foil or metallic laminate, wherein the capacitance between the conductive foil or metallic laminate of the package and a fixed electrode is

measured when the package is subjected externally to a partial vacuum (col. 1, lines 34-40).

In the present application, independent claim 21 recites an in-process control method in a production run of an on-going packaging process for pharmaceutical formulations to test the leaktightness of a sealed container that holds a pharmaceutical active substance formulation in a chamber, the method comprising the steps of a) acting upon the sealed container with a gas such that any increase of the gas inside the chamber can be analyzed; b) removing a sample from the chamber; and c) analyzing the sample for the presence of the gas.

The Applicant respectfully submits that, even assuming, *arguendo*, that Veillard may be properly combined with Vinton as proposed by the Examiner, the resulting combination does not provide all the features of the present invention as recited in independent claim 21. In particular, unlike the presently claimed invention, the cited combination does not provide a method for acting on a sealed container or removing a sample from a sealed container.

Contrary to the Examiner's assertion, Veillard does not teach or even suggest a method for testing "sealed containers," *per se*. Veillard teaches a container that is sealed by an impermeable plug only for the purpose of verifying its impermeability. Indeed, Veillard would not need a "plug" at all if the container was truly sealed. In other words, an impermeable plug is unnecessary for sealed containers. Veillard describes that the impermeable plug closes the container before the test, and the

impermeable plug is opened after the test. Veillard refers to a "sealed enclosure" only once after stating that the impermeable plug closes the container.

Moreover, since the container of Veillard is not a sealed container, *per se*, Veillard does not teach or even suggest removing a sample from a chamber in a sealed container. Instead, Veillard teaches that the impermeable plug is merely opened and a sample is removed from the container, for example, via a pump.

Furthermore, Vinton does not provide the disclosure lacking in Veillard. Significantly, since Vinton uses electrical properties of the sealed container to determine hermetic integrity, as opposed to the present invention that uses a tracer gas, Vinton cannot teach the step of physically removing a sample from a chamber in a sealed container. Also, Vinton forms a vacuum around the sealed container to be tested, as opposed to the present invention that acts upon a sealed container with a gas. In fact, Vinton, taken as a whole, clearly teaches away from the present invention.

In light of the foregoing, the Applicant respectfully submits that the present invention as recited in claim 21 is not obvious based on Veillard in view of Vinton and, therefore the §103(a) rejection of claim 21 should be reconsidered and withdrawn. In addition, since claims 22-26, 30, 31, and 33-39 ultimately depend from independent claim 21, the Applicant respectfully submits that claims 22-26, 30, 31, and 33-39 are not obvious based on the references cited by the Examiner and, therefore the §103(a) rejection of claims 22-26, 30, 31, and 33-39 should be reconsidered and withdrawn.

The Applicant respectfully requests favorable consideration of this application, and that this application be passed to allowance.

Respectfully submitted,

Date: February 24, 2005

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